# Permissive weight bearing in trauma patients with fracture of the lower extremities

Gepubliceerd: 01-09-2016 Laatst bijgewerkt: 18-08-2022

Hypothesis 1: 1A; Included patients have better early recovery at function level (as measured with the Brunnstrom Fugl-Meyer (BFM) test), 1B; better outcome at activity level (as measured with the Lower Extremity Functional Scale (LEFS)), 1C; better...

**Ethische beoordeling** Positief advies **Status** Werving gestart

Type aandoening

Onderzoekstype Interventie onderzoek

# Samenvatting

#### ID

NL-OMON27998

**Bron** 

NTR

Verkorte titel

**PWB** 

#### **Aandoening**

Trauma, permissive weight bearing, rehabilitation, fractures of the lower extremitiets.

### **Ondersteuning**

**Primaire sponsor:** Maastricht Universitair Medisch Centrum

Adelante Rehabilitation Centre, Hoensbroek

Zuyderland Hospital, Heerlen

University of Aachen Medical Center (Germany)

Overige ondersteuning: Maastricht Universitair Medisch Centrum

Adelante Rehabilitation Centre, Hoensbroek

Zuyderland Hospital, Heerlen

University of Aachen Medical Center (Germany)

# Onderzoeksproduct en/of interventie

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

Main outcome variable:<br>- ADL (LEFS) with LEFS<br>>

Outcome variables for functional outcome: <br

- Score on LEFS at 0,1, 3, 6, 12, and 26 weeks post-surgery <br/>
<br/>
<br/>
<br/>
<br/>
- Score on LEFS at 0,1, 3, 6, 12, and 26 weeks post-surgery

LEFS: is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The LEFS can be used by clinicians as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals. The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention. The questionnaire consist of 80 points. The lower the score the greater the disability.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

The development of surgical fracture care boosted 50 years ago and is improving since, while emphasis on post-surgical care facilitating optimal bone healing and function restoration remains sparse. The positive effects of early weight bearing, both for fracture healing and for maintaining muscle and bone mass, are well known. However, little is known about the association between the amount or timing of weight bearing and bony consolidation or functional recovery. As a result, weight bearing rehabilitation is often cautious and led by existing dogmas, such as the fear for secondary dislocation of the fracture or failure of a mechanical construct. We have developed an early permissive weight bearing post-surgery rehabilitation protocol, where progression of weight bearing is guided by the subjective experience (e.g. pain, weight bearing tolerance) of the patient and therapist, and objective parameters (e.g. temperature, edema, using insoles) are registered. This protocol is based on our clinical experience focused on patient centered rehabilitation and has been validated and implemented in Adelante rehabilitation centre since 2005. Retrospectively we retrieved the medical records and recorded the complications during the time phase the new protocol was used. We found a complication rate of 10 percent. We developed a treatment- and evaluation protocol for permissive weight bearing (PROMETHEUS protocol, see appendix A) to document and to record the weight bearing milestones (e.g. walking with 2 crutches, walking with 2 canes, walking with one cane and walking without any walking aids) in a database. We started practicing the PROMETHEUS protocol method guided by subjective experience of patient and therapist and objective parameters. Hereby, the therapy progression is measured in quality of performing an activity (walking) and not in percentage of bodyweight or in kilogram load bearing. In this proposal we want to compare our new protocol (PROMETHEUS) to the existing AO treatment guidelines in a prospective multi-center trial. This study will be performed in patients with peri- or intra-articular fractures of the pelvis and lower extremity after surgical treatment in which existing protocols do not allow early full weight bearing in the first 6-12 weeks.

#### Doel van het onderzoek

Hypothesis 1: 1A; Included patients have better early recovery at function level (as measured with the Brunnstrom Fugl-Meyer (BFM) test), 1B; better outcome at activity level (as measured with the Lower Extremity Functional Scale (LEFS)), 1C; better participation (as measured with the SF-36) and 1D; a better quality of life (as measured with the EQ-5D-5L) in the first 6 months post-surgery when they are treated according to the permissive weight bearing protocol compared to patients treated according to standard AO guidelines. It is expected that long-term (1 year) functional outcome will be similar between the treatment groups and will be not the primary aim of this study. We have chosen for these three scales to cover the major outcome levels in the ICF model.18

Hypothesis 2: The permissive weight bearing protocol results is more cost-effective compared to the restricted weight bearing protocol and current guidelines.

Hypothesis 3: The rate of complications (e.g. failure of osteosyntheses, secondary displacement of fracture parts, non-union, infections) is equal or lower in patients who are treated according to the permissive weight bearing protocol compared to patients treated according to standard AO guidelines in the surgery reference.

#### Onderzoeksopzet

The subjects have to complete questionnaires in week 0,1,3,6,12,26. After 6 months the follow-up will be ended.

#### Onderzoeksproduct en/of interventie

Permissive weight bearing group: Treatment according to the PROMETHEUS protocol (treatment- and evaluation protocol), patients will have an optimal/intensive weight bearing treatment. The protocol contains a number of weight bearing milestones (e.g. walking with 2 crutches, walking with 2 canes, walking with one cane and walking without any walking aids). The treating physiotherapist or physician records the date these milestones are reached in the study database.

# Contactpersonen

#### **Publiek**

Maastricht universitair medisch centrum - Afd. Traumatologie

Pishtiwan Kalmet P. Debyelaan 25

Maastricht 6229 HX The Netherlands 06-27020227

## Wetenschappelijk

Maastricht universitair medisch centrum - Afd. Traumatologie

Pishtiwan Kalmet P. Debyelaan 25

Maastricht 6229 HX The Netherlands 06-27020227

# **Deelname** eisen

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Trauma patients with surgically treated fractures of the lower extremities
- Age > 18
- No additional problem of rheumatic orthopaedic or neurological nature of the lower extremities (i.e. primary coxarthrosis or gonarthrosis)
- Being able to understand the questionnaires and measurement instructions

# Belangrijkste redenen om niet deel te kunnen nemen

#### (Exclusiecriteria)

- Amputation patients (Upper limb, lower limb, feet) and bilateral fractures of the lower extremities.
- Severe non fracture related comorbidity of the lower extremity
- · No informed consent
- Additional complaints who influence the measurements

# **Onderzoeksopzet**

#### **Opzet**

Type: Interventie onderzoek

Onderzoeksmodel: Parallel

Toewijzing: Niet-gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: N.v.t. / onbekend

#### **Deelname**

Nederland

Status: Werving gestart

(Verwachte) startdatum: 01-01-2017

Aantal proefpersonen: 120

Type: Verwachte startdatum

# **Ethische beoordeling**

Positief advies

Datum: 01-09-2016

Soort: Eerste indiening

# **Registraties**

# Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

# Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

#### In overige registers

Register ID

NTR-new NL5889 NTR-old NTR6077

Ander register METC Zuyderland : 16-N152

# Resultaten